## IAP2 Rec'd PCT/PTO 12 DEC 2005

PTO-1390 (Rev. 07-2005)
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TRANSMITTAL LETTER TO THE UNITED STATES

ATTORNEY'S DOCKET NUMBER

DESIGNATED/ELECTED OFFICE (DO/EO/US)			PRD2076f-PCT-USA					
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (If known, see 37 CFR 1.5)					
	TIONAL APPLICATION NO. PCT/EP2004/051048	INTERNATIONAL FILING DATE 7 June 2004	PRIORITY DATE CLAIMED 10 June 2003					
TITLE OF	TITLE OF INVENTION NOVEL FORMULATIONS OF OPIOID-BASED TREATMENTS OF PAIN COMPRISING							
	SUBSTITUTED 1,4-DI-PIPERIDIN-4-YL-PIPERAZINE DERIVATIVES  APPLICANT(S) FOR DO/EO/US Frans Eduard Janssens, François Maria Sommen, Benoit Christian Albert Chislain De							
Applicant		enaerts, Yves Emiel Maria Van Ro ates Designated/Elected Office (DO/EO	osbroeck, and Theo Frans Meert /US) the following items and other information:					
(22)	This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.							
2. 🗆 -	This is a SECOND or SUBSEQUENT s	ubmission of items concerning a submission	n under 35 U.S.C. 371.					
3.	This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.							
4.	The US has been elected (Article 31).		•					
5. X	A copy of the International Application	n as.filed (35 U.S.C. 371(c)(2))						
	a. X is attached hereto (required	only if not communicated by the Internation	al Bureau).					
	b. has been communicated by	the International Bureau.						
	c. is not required, as the applic	cation was filed in the United States Receiving	ng Office (RO/US).					
6. 📙	An English language translation of the	e International Application as filed (35 U.S.C	. 371(c)(2)).					
	a. is attached hereto.							
(चर)	b. has been previously submit	ted under 35 U.S.C. 154(d)(4).						
7. X	Amendments to the claims of the Inte	rnational Application under PCT Article 19 (	35 U.S.C. 371(c)(3))					
	a are attached hereto (requir	red only if not communicated by the Internat	ional Bureau).					
	b. have been communicated	by the International Bureau.						
	c. have not been made; howe	ever, the time limit for making such amendm	ents has NOT expired.					
	d. $X$ have not been made and w	vill not be made.	·					
8.	An English language translation of the	e amendments to the claims under PCT Arti	cle 19 (35 U.S.C. 371(c)(3)).					
9. X	An oath or declaration of the inventor	(s) (35 U.S.C. 371(c)(4)).						
10.	An English language translation of the Article 36 (35 U.S.C. 371(c)(5)).	e annexes of the International Preliminary Ex	xamination Report under PCT					
Items	11 to 20 below concern document(s)	or information included:						
11.	An Information Disclosure Statement	under 37 CFR 1.97 and 1.98.						
12.	An assignment document for recording	g. A separate cover sheet in compliance wit	h 37 CFR 3.28 and 3.31 is included.					
13. 🛚	A preliminary amendment.							
14. 🔲	An Application Data Sheet under 37 C	CFR 1.76.						
15. 🔲	A substitute specification.							
16. X	A power of attorney and/or change of	address letter.						
17.	A computer-readable form of the sequ	ence listing in accordance with PCT Rule 1	3ter.2 and 37 CFR 1.821- 1.825.					
18. X	A second copy of the published Intern	ational Application under 35 U.S.C. 154(d)(	4).					
19.	A second copy of the English languag	e translation of the international application	under 35 U.S.C. 154(d)(4).					

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 232313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3

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U.S. AFFLICATE	<b>U/5</b> 6	0476	PCT/EP200					
20. Other items or information: Published Application WO 2004/110415 A2 and A3 w/Search Report Attached Power of Attorney for Each Inventor (6) Express Mail Certificate								
The follow	ing fees have b	peen submitted			CALCULATIONS	PTO USE ONLY		
,				\$ 300.00	1			
22. X Examin	ation fee (37 C							
If the written opinion by IPEA/US All other situations	indicates all c	\$ 200.00						
If the written opinion IPEA/US in Search fee (37 CFF International International Search	dicates all clain (1.445(a)(2)) h Il Searching Au In Report prepar Inmunicated to	\$ 400.00						
TO	TAL OF 21, 2	2 and 23 =	· · · · · · · · · · · · · · · · · · ·	-	900.00	)		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof.								
Total Sheets E	xtra Sheets		additional 50 or fraction up to a whole number)	RATE		·		
- 100 =	/50 =			x \$250	\$ 0.00	·I		
Surcharge of \$130.0 after the date of cor	urcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration ter the date of commencement of the national stage (37 CFR 1.492(h)).				\$ 0,00			
CLAIMS	NUMB	BER FILED	NUMBER EXTRA	RATE	\$			
Total claims	17	- 20 = `	0	x \$ 50	\$ 0			
Independent claims	3	- 3 =	0	× \$200	\$ 0			
MULTIPLE DEPEN	MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360				\$ 0			
TOTAL OF ABOVE CALCULATIONS =					\$ 900.00			
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.				ed by 1/2.				
SUBTOTAL =					\$ 900.00			
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).					\$	0.00		
TOTAL NATIONAL FEE =					\$	900.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property +					\$	0.00		
TOTAL FEES ENCLOSED =					\$	0.00		
				Amount to be refunded:	\$			
				Amount to be charged	. \$			

10/560476 19 DEC 2008 - PTO-1390 (Rev. 07-2005)

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A check in the amount of \$ to cover the above fees is enclosed. b. **X** Please charge my Deposit Account No. 10-0750 in the amount of \$ 900.00 to cover the above fees. A duplicate copy of this sheet is enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 10-0750 . A duplicate copy of this sheet is enclosed. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: Hal B. Woodrow, Esq. One Johnson & Johnson Plaza Hal B. Woodrow New Brunswick, NJ 08933 NAME U.S.A. 32,501 REGISTRATION NUMBER

Docket No. PRD2076f-PCT-USA

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Frans Eduard Janssens et al.

For:

NOVEL FORMULATIONS FOR OPIOID-BASED TREATMENTS OF PAIN.

COMPRISING SUBSTITUTED 1,4-DI-PIPERIDIN-4-YL-PIPERAZINE

**DERIVATIVES** 

#### **Express Mail Certificate**

"Express Mail" mailing number:

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Date of Deposit:

December 12, 2005

I hereby certify that this entry into the National Phase pursuant to 35 USC 371 contains complete application:

$\boxtimes$	Express Mail Certificate	(1 page)
	Return Receipt Postcard	(1 page)
$\boxtimes$	PCT FORM 1390 Transmittal	(3 pages)
$\boxtimes$	Copy of International Application as filed	(83 pages)
$\boxtimes$	Declaration of Inventors	(4 pages)
$\boxtimes$	Power of Attorney for Inventors	(6 pages)
П	Assignment & Recordal Cover Sheet	(2 pages)
	Preliminary Amendment	(9 pages)
$\overline{\boxtimes}$	WO 2004/110415 A2 & A3	(45 pages)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee; service under 37 CFR 1.10 on the date indicated above is addressed to the Mail Stop: PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450...

#### Laurie Phillips

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### /Laurie Phillips/

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